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IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardian Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR RESPONDENT

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QUESTION PRESENTED

Whether the Federal Rules of Evidence require that expert scientific testimony have an adequate foundation, judged by accepted scientific standards and processes for validating scientific claims.

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BRIEF FOR RESPONDENT

STATUTES INVOLVED

An appendix to this brief reprints a number of the Federal Rules of Evidence at issue in this case.

STATEMENT

These are two consolidated product liability cases alleging that the drug Bendectin caused petitioners' limb reduction defects. Both courts below concluded that respondent was entitled to summary judgment on the ground that petitioners had failed to come forward with admissible scientific evidence of causation necessary to support a rational jury verdict in their favor. That conclusion was legally proper and should be affirmed.

1. *Background.* "Morning sickness" is experienced by a large proportion of women during the first trimester of pregnancy. The result often is not only acute discomfort but weight loss and lack of nourishment that are unhealthy for both mother and fetus. In some instances, morning sickness leads to severe health problems, necessitating hospitalization. *See* Skolnick, *Key Witness Against Morning Sickness Drug Faces Scientific Fraud Charges*, 263 J. Amer. Med. Ass'n 1468 (1990).

Bendectin is an anti-nausea drug that treats this affliction. The drug was introduced in 1956 and was available until the beginning of 1983, when the costs of litigation and insurance forced its manufacturer to discontinue production. During that period, Bendectin was prescribed by physicians to approximately 30 million women, 17.5 million of whom lived in this country. *See Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992).

In the 1970s, individual case reports noted that Bendectin had been taken by the mothers of certain children born with birth defects. Because as many as 2-3% of all babies are born with some birth defects, and Bendectin was so widely taken, chance alone produces an inevitable overlap of Bendectin and birth defects. Against the background of the thalidomide disaster of the 1960s, however, the case reports produced concern about whether Bendectin in fact causes birth defects. Beginning in 1977, law suits were filed against the producer of Bendectin.

The medical scientific community responded to the concerns about Bendectin with intense study. Epidemiologists first approached the question whether Bendectin was causing birth defects by examining data on large numbers of women having babies and looking for any unusually high incidence of any birth defects among women who took Bendectin. These ("cohort") studies detected no causal connection between the incidence of any particular defects, or of defects overall, and the use of Bendectin. In

1980, based primarily on those studies, the Food and Drug Administration conducted a comprehensive review of the safety of Bendectin and concluded that the "'available data do not demonstrate an association between birth defects and Bendectin.'" Green, *Expert Witnesses and Sufficiency of Evidence In Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U. L. Rev. 643, 679-80 (1992) (quoting *Department of Health and Human Services News*, No. P80-45 (Oct. 7, 1980)).

Inevitably, when numerous studies are performed to look for an association between two phenomena (*e.g.*, Bendectin use and birth defects), there will be a range of correlations found, even when, over all, the studies show no positive correlation. The essential question in such a situation, answerable only through attempts at replication in other data, is whether the higher numbers reflect nothing more than expected variation among study samples or whether there actually is a positive correlation—here, whether Bendectin and birth defects are in fact related. A powerful tool used by epidemiologists to address this question is a study that examines data on women who gave birth to babies with the specific types of defect in question and asks if a disproportionate number of these women had been exposed to the suspected cause of the birth defect. In the case of Bendectin, these ("case-control") studies did not demonstrate any causal connection between Bendectin and any defect.[1]

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[1] Drs. Cordero and Oakley, of the Centers for Disease Control, summarized the results of all of the Bendectin studies:

> Several case reports of limb reduction defects have raised some concerns about the safety of Bendectin. The hypothesis on the teratogenicity of this drug has been tested in both cohort and case-control studies. . . . When all the studies are considered, it is possible to exclude a risk of birth defects of over 1.2 per 1000. If there is a risk in the use of that drug, it should be less than 0.12%, which is significantly less than the 2-3% risk that any pregnancy has just by chance for serious malformation. This is one example where case reports raised concern

In all, there have been more than 30 published studies involving 130,000 patients relating to the possible teratogenic effect of Bendectin. J.A. 238; *Turpin*, 959 F.2d at 1349 (35 published studies). The remarkable fact about this entire body of research is that no published study has concluded that there is a causal connection, or even a reproducible or consistent association, between Bendectin and any birth defect, and no published study has found any statistically significant association between Bendectin and the sort of birth defects (limb reduction) at issue here. *See* J.A. 212-26, 235, 238. The power of these individual studies is still more dramatic when they are aggregated: "*In toto*, they show no difference in the risk of birth defects between those infants whose mothers had taken Bendectin during the first trimester of pregnancy and those infants whose mothers had not." J.A. 33 (aff. of Dr. Lamm, respondent's expert here but originally court-appointed expert in S.D. Ohio class action); *see also* Einarson, *et al.*, *A Method for Meta-Analysis of Epidemiological Studies*, 22 Drug Intelligence and Clinical Pharmacy 813 (1988) (aggregating 17 Bendectin studies).[2]

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about a specific teratogenic action when epidemiologic studies could show that there was no association.

Cordero and Oakley, *Drug Exposure During Pregnancy: Some Epidemiologic Considerations*, 26 Clinical Obstetrics and Gynecology 418, 424-25 (June 1983) (footnote omitted).

[2] In Canada, where the same medication as Bendectin is still widely used, the government recently "requested an independent review by an expert panel." *Report on the Safety of Bendectin/Diclectin for Use in the Management of Nausea and Vomiting in Pregnancy* (Aug. 11, 1989), *reprinted at* J.A. 212-26. After noting that "[t]here has been no prescription drug that has been more extensively studied for reproductive toxicity[,]" the report concludes that "the prescribing of Bendectin to a human population presents no measurable reproductive risks" and that "[i]t would be a disservice to Canadian women to withdraw this drug from the market." *Id.* at 213, 216.

Faced with this massive body of uniform scientific research, plaintiffs in Bendectin cases responded with four kinds of evidence to try to show causation: (1) studies of animal cells that have been injected with extremely high doses of Bendectin (*in vitro* studies); (2) studies of pregnant animals that have been given extremely high doses of Bendectin (*in vivo* studies); (3) chemical analyses comparing Bendectin to other substances that are alleged teratogens; and (4) "reanalyses" of certain of the published epidemiological studies, claiming (contrary to the published findings) to show that Bendectin use does correlate with limb defects. J.A. 232-35; *see, e.g.*, *Turpin*, 959 F.2d at 1358-60; *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 313-14 (5th Cir. 1989); *Lynch v. Merrell-Nat'l Lab.*, 830 F.2d 1190, 1194-96 (1st Cir. 1987).

With extraordinary consistency, this evidence has been found insufficient to prove causation—by most juries and by most courts (on summary judgment, after verdict, or on appeal). Indeed, of the roughly 2000 Bendectin cases that have been filed—the vast majority of which have already reached final judgment—only one case has resulted in an affirmed jury verdict for the plaintiff. *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986). Five circuits, including the court below, have ruled as a matter of law that plaintiffs' evidence is insufficient. *Turpin*, *supra* (6th Cir.); *Brock*, *supra* (5th Cir.); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989); *Lynch*, *supra* (1st Cir.).[3] And juries in several separate trials—including, notably, a multi-district case involving 818 consolidated actions—returned defense ver-

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[3] The Third Circuit in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), remanded for a more detailed analysis of the foundation for the Bendectin plaintiff's evidence. On remand, the district court found the evidence utterly unfounded and insufficient. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042 (D.N.J. 1992).

dicts that were upheld by the courts. *See, e.g., Wilson v. Merrell Dow Pharmaceuticals, Inc.*, 893 F.2d 1149 (10th Cir. 1990); *Will v. Richardson-Merrell, Inc.*, 647 F. Supp. 544 (S.D. Ga. 1986); *In re Richardson-Merrell, Inc. "Bendectin" Products Liab. Litig.*, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988); *Cosgrove v. Merrell Dow Pharmaceuticals, Inc.*, 788 P.2d 1293 (Idaho 1990).

Nevertheless, the burden of this avalanche of litigation forced its manufacturer, respondent Merrell Dow, to cease production of Bendectin in 1983, because the cost of insurance rose to almost equal the entire income from sale of the drug. *Brown v. Superior Court*, 751 P.2d 470, 479 (Cal. 1988).[4] With Bendectin now unavailable in the United States (though it remains approved by the FDA), there is no medication of proven effectiveness that physicians may prescribe for the treatment of morning sickness. *See* 1 I. Chalmers *et al., Effective Care of Pregnancy and Childbirth* 501 (1989). As a result, there has been "a two-fold increase in hospitalizations caused by severe nausea and vomiting in pregnancy since the disappearance of Bendectin." Skolnick, *supra*, at 1473.

2. *This Litigation.* The Daubert petitioners filed suit on September 17, 1984, alleging that Bendectin had caused limb reduction birth defects in Jason Daubert, who was born on July 26, 1973. Petitioner DeYoung filed suit on May 11, 1984, alleging that Bendectin had caused limb defects in Eric Schuller, who was born on December 13, 1980. The two cases, initially filed in California Superior Court, were removed to federal court on diversity grounds and consolidated. On August 2, 1989, Merrell moved for summary judgment, arguing that petitioners lacked sufficient evidence to raise a triable issue regarding causation.

[4] Respondent was formerly known as Richardson-Merrell, Inc., the successor to the company (Wm. S. Merrell Co.) that developed and initially marketed Bendectin. For Rule 29.1 statement, see Br. in Opp. i-iv.

a. The district court granted Merrell's motion on November 1, 1989. The court began by noting that "[t]he plaintiff must show that defendant's [product] 'was more probably than not the proximate cause of the accident' to defeat summary judgment and take the issue to a jury." J.A. 228-29 (quoting *Bieghler v. Kleppe*, 663 F.2d 531, 553 (9th Cir. 1980)). Applying that standard—and taking into account the decisions of several other courts in Bendectin cases—the district court scrutinized the proposed testimony of eight expert witnesses relied on by petitioners and concluded that their opinions did not raise a reasonably disputable question for the jury on the issue of causation.[5]

The court reasoned that, given the vast body of epidemiological data concerning Bendectin's effects on human subjects, "expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the sufficient foundation necessary under [Fed. R. Evid.] 703." J.A. 234-35 (citations omitted). Consequently, the court ruled, three of the four types of evidence relied on by petitioners—animal cell studies, live animal studies, and chemical structure analyses—could not by themselves raise a reasonably disputable jury issue on causation. The court next found that petitioners' fourth type of evidence—a study that "recalculated a previously published study . . . to show that there actually was a significant relation between Bendectin and birth defects" (*id.* at 236) (citation omitted)—was also inadequate to put genuinely in issue the numerous published studies showing no such relation. The court emphasized that petitioners' "'study' was apparently never

[5] Petitioners relied on affidavit and deposition evidence virtually identical to the evidence before the courts in *Brock*, *Lynch*, and *Richardson*. In all three of those cases, the courts of appeals had concluded that the experts' reanalyses of the published epidemiological studies, coupled with their reliance on animal and chemical studies, did not provide a basis for allowing the issue of causation to go to the jury.

published or subjected to peer review" and held that the conclusory assertion by petitioners' experts that their "study" showed a "'statistically significant association [between Bendectin and birth defects]' . . . is insufficient to take this matter to a jury." *Id.* at 236 (internal citation omitted).

b. The Court of Appeals for the Ninth Circuit affirmed. The court began with the proposition that "[e]xpert opinion based on scientific technique 'is admissible if it is generally accepted as a reliable technique among the scientific community.'" J.A. 238 (quoting *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985), and citing *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)). The court explained that this standard is grounded in the recognition that scientific "evidence creates a substantial danger of undue prejudice or of confusing the issues or of misleading the jury . . . because of its aura of special reliability and trustworthiness." *Ibid.* (internal quotation and citation omitted). It is important, the court added, that "the answer to the question about the reliability of a scientific technique or process . . . not vary according to the circumstances of each case. It is therefore inappropriate to view this threshold question of reliability as a matter within each trial judge's individual discretion." *Id.* at 238-39 (internal quotation and citations omitted).

Applying these principles to the scientific evidence at issue in this case, the court first held that the animal studies and cell-structure analyses put forth by petitioners are "insufficient to establish a link between Bendectin and birth defects." *Id.* at 239. The court pointed out that three other circuits had already reached the same conclusion. J.A. 239-40 (citing *Brock*, 874 F.2d at 313-15; *Richardson*, 857 F.2d at 830; *Lynch*, 830 F.2d at 1194). The court observed that those circuits had reached that conclusion "in part because the plaintiffs' own experts acknowledged the need to verify such data with epidemiological evidence." J.A. 239-40.

The Ninth Circuit then turned to the data relating to humans that petitioners had put forward—that is, their reanalysis—and also found it wanting. The court explained that "the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field." *Id.* at 240. The reanalyses proffered by petitioners, however, "were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation." *Id.* at 241 (footnote omitted). The court thereupon concluded that "[f]or the convincing reasons articulated by our sister circuits, we agree with the district court that the available animal and chemical studies, together with plaintiffs' expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused plaintiffs' injuries." *Ibid.*

INTRODUCTION AND SUMMARY OF ARGUMENT

In opposing summary judgment, petitioners rely exclusively on expert testimony stating that Bendectin causes limb defects in general and their limb defects in particular. They agree that this testimony, to be admissible, must satisfy the requirements of Rule 702, the sole provision in the Federal Rules that authorizes its use. They contend, however, that Rule 702 imposes only two requirements: first, a general determination in the case that this type of "specialized knowledge will assist the trier of fact"; second, a determination that "the witness 'is qualified as an expert' in that specialized field." Pet. Br. 31. That position, which has not been adopted by a single federal court of appeals, is contrary to the language, structure, and policies of the Rules, because it omits a crucial additional requirement of Rule 702—namely, that the specific testimony of each expert have an adequate foundation, judged by the accepted standards of the expert's field.

It is the judge's fundamental duty under the Rules to screen evidence for admissibility to ensure that the body of evidence provides a rationally reliable basis for judgment. This screening requires not only relevancy of evidence, as petitioners recognize, but also, as petitioners almost completely ignore, an adequate foundation for evidence. It is just such a reliable foundation, substituting for the usual requirement of personal knowledge applicable to *non*-expert testimony, that Rule 702 demands for expert testimony. In particular, by restricting expert testimony to "scientific, technical, or other specialized *knowledge* [that] will assist the trier of fact," Rule 702 demands that an expert's testimony be well-grounded in the standards generally followed in his or her field for validating—establishing the truth of—assertions of the type offered. And Rule 703 specifically confirms Rule 702's insistence on community validation standards by allowing hearsay evidence to be part of the foundation for an expert's claims only when the evidence is "of a type reasonably relied upon by experts in the particular field."

As applied to "*scientific* . . . knowledge" in particular, Rule 702 looks to two ways to determine the necessary foundation—(1) the out-of-court scientific process of scrutiny and verification; (2) an in-court assessment of whether the data and reasoning underlying a claim meet scientific standards. This approach reflects the approach followed by the scientific community itself for validating assertions. Certain general principles—*e.g.*, light travels at 186,000 miles per second—are validated through widespread dissemination to other experts in the field, who then test the assertion by analyzing the first scientist's reasoning and attempting to replicate the results. Other, typically non-generic, conclusions—*e.g.*, Jones has an illness—are validated by assuring that the customary scientific methods for making such determinations have been used.

In this case, the testimony proffered by petitioners' experts does not satisfy either of the standards used by the scientific community for validating assertions. Petitioners' experts claim, at a minimum, that Bendectin causes limb defects (in some number of babies who otherwise would not have such defects). In the field of science, that kind of general claim about a substance's "inherent" properties is ordinarily validated through widespread dissemination to, and scrutiny by, the community. That foundational requirement was not met here. In any event, even if an in-court assessment of scientific method could suffice to establish an adequate foundation for testimony about Bendectin's inherent qualities, petitioners have not satisfied that requirement. Their primary reliance on animal studies and chemical analyses in the face of a near-library of available human (epidemiological) data does not comport with community standards. And to the extent that petitioners' experts did consider human data, their patently biased data-selection process, coupled with their inability to explain why they ignored the overwhelming body of data that contradict their conclusion, likewise runs afoul of rudimentary scientific standards.

As we will also show, essentially the same reasoning as applies under Rule 702 would, in this case, render the evidence at issue inadmissible under Rule 703 and under Rule 403. In addition, the unreliability of the foundation means that summary judgment in this case is properly affirmed on the ground that, even if admissible, the evidence is simply too weak to sustain petitioners' challenge to the volume of published causation evidence supporting Merrell Dow.

ARGUMENT

THE TESTIMONY OF PETITIONERS' EXPERTS NECESSARY TO WITHSTAND A MOTION FOR SUMMARY JUDGMENT WAS PROPERLY EXCLUDED BECAUSE IT LACKS AN ADEQUATE FOUNDATION AS REQUIRED BY RULE 702 OF THE FEDERAL RULES OF EVIDENCE.

Petitioners begin their challenge to the Ninth Circuit's decision by arguing that it improperly rests on "a judge-made rule of evidence independent of the Federal Rules." Pet. Br. 14. But the Ninth Circuit decided the case, and we defend the holding, on the basis of the Federal Rules. We agree with the Ninth Circuit that Rule 702, which authorizes the admission of expert testimony in the first place, requires such testimony to have an adequate foundation as judged by community standards, a conclusion strongly reinforced by Rule 703.[6]

A. Rule 702 Bars The Admission Of Expert Testimony That Lacks A Foundation Based On The Accepted Standards Of Validation In The Expert's Field.

Rule 702 allows an expert to testify only to inferences and conclusions that are validated under, or derived from, the accepted standards and methods of that field. This construction rests on a straightforward reading of Rule 702's language and is supported by the language of Rule 703, which governs the "bases of opinion testimony by

[6] The arguments of both petitioners (C.A. Reply Br. 9) and respondent (C.A. Br. 17-18) focused on Rule 702 in the court of appeals, and the Ninth Circuit's opinion relies (J.A. 238) on the legal standard set out in its earlier decision in *United States v. Solomon*, 753 F.2d 1522 (9th Cir. 1985), which expressly relied on Rule 702 of the Federal Rules (*id.* at 1525). The Ninth Circuit also pointed out (J.A. 240) that several other courts, following the same foundational approach to expert testimony, had relied on Rule 703, rather than Rule 702. *See, e.g., Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 830-31 (D.C. Cir. 1989); *see also* cases cited at note 24, *infra*.

experts." It also comports with the structure of the Rules as a whole, which assign to the court (and not the trier of fact) the responsibility for ensuring that *all* evidence rests on a reliable foundation. It is further buttressed by the fact that, when the Federal Rules of Evidence were enacted in 1975, the federal courts routinely made this kind of foundational inquiry with respect to expert scientific testimony, and there is no reason to suppose, as petitioners do, that Congress intended to eliminate this well-established evidentiary practice without ever saying so.[7]

1. *The Language of the Rules, Reinforced by the Advisory Committee Notes, Demonstrates that an Expert's Testimony Must Be Validated, to the Extent Possible, According to Accepted Standards in the Field.*

Rule 702 states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

The critical term "knowledge" demands more than individual belief or speculation, but instead refers to inferences or assertions that are grounded in the standards reliably used to support such claims. Other language of Rule 702, as well as Rule 703, confirms this interpretation.

a. *Scientific Knowledge.* Rule 702 requires that what an expert is testifying to itself be "scientific, technical,

[7] Although this case involves only scientific testimony, the analysis in the text applies as well to "technical or other specialized knowledge" under Rule 702. Indeed, unless a field has a set of rational and well-recognized standards of validation, testimony in that field cannot be admitted because it is not "knowledge" but superstition or belief. That is why astrologers and phrenologists are not permitted to testify in federal court.

or other specialized knowledge." Thus, the Rule says that when "scientific . . . knowledge will assist the trier of fact . . . , a [qualified] witness . . . may testify *thereto*." (Emphasis added.) The critical connecting term "thereto" unambiguously requires that the substance of the expert's testimony be "scientific knowledge." The testimony may, of course, be "in the form of an opinion or otherwise." But as the Advisory Committee Note indicates, the Rule uses "opinion" *not* to refer to general "principles" themselves, but only to the application of such principles, through inferences, to the particular case. Rule 702, Adv. Comm. Note ("dissertation or exposition of scientific or other principles" is not "opinion," which is "suggesting the inference which should be drawn from applying the specialized knowledge to the facts"). And even when offering an "opinion," a scientific expert must be testifying "[]to" "scientific knowledge."

These words naturally mean that an expert must be testifying to more than merely his or her own view on a scientific issue. Rule 702 does not allow an expert to offer "beliefs" or "hypotheses" or "theories" or "claims" or "assertions" or "evidence" or "testimony"; instead, it limits expert testimony to "knowledge." Even by itself, "knowledge" ordinarily requires, at a minimum, appropriate validation for the proposition—*i.e.*, "good grounds" for the belief based on what is known. *See Webster's Third New International Dictionary* 1252 (1986). And when used as part of the phrase "scientific, technical, or other specialized knowledge," the term naturally refers to grounds that are deemed good by the relevant scientific, technical, or other specialized field—that is, to claims that are validated, or derived, according to the accepted standards in the relevant field. *See* J. Kourany, *Scientific Knowledge: Basic Issues in the Philosophy of Science* 112 (1987) (hypotheses "must prove their mettle" to become "part of scientific knowledge"). Rule 702's language, naturally read, thus requires validation to the extent possible—*i.e.*, a foundation, or good reason for acceptance

as valid—based on established standards in the expert's field.[8]

Rule 702's use of the word "knowledge" to require validation by appropriate standards, or more than mere personal views, is consistent with the usage of that term in other Rules and the Advisory Committee Notes. First, it is supported by Rule 602. In referring to "personal *knowledge*," Rule 602 requires appropriate validation for the testimony in personal observation, which, of course, is generally thought to be the most reliable way for establishing the truth of non-expert factual assertions. *See* Rule 602, Adv. Comm. Note (witness "'must have had an opportunity to observe, and must have actually observed the fact'" to establish the "foundation" requirement of "personal knowledge"). Moreover, the "*personal* knowledge" of Rule 602 contrasts directly with the more-than-merely-personal "scientific, technical, or other specialized knowledge" of Rule 702.

Similarly, the Advisory Committee Note to Rule 702, in referring to a "dissertation or exposition of scientific or other principles," plainly treats the "knowledge" referred to by the Rule as more than mere personal opinion. So, too, when the Advisory Committee Note observes that "there are other techniques for supplying" the "scientific, technical, or other specialized knowledge," it necessarily treats this knowledge as something other than any particular witness's own beliefs (since it can be supplied

[8] It is, of course, perfectly conceivable for each of several competing scientific (or other expert) claims to be validated to the extent possible at any given time. The very reason that scientists can disagree, and that scientific knowledge advances as it does, is that what is known at a particular moment does not uniquely predetermine all answers to new questions. Accepted standards and available evidence thus may not rule out either of two competing, but well-reasoned, conclusions. By the same token, however, they do rule out some answers. What validation means, therefore—all it *can* mean, given the ever-evolving body of knowledge—is good reason for acceptance as true, based on what is known at the time.

without a witness at all). And, notably, the two obvious alternative methods of supplying such knowledge—judicial notice under Rule 201, where there is no need for elaboration or explanation on the witness stand; and learned treatises under Rule 803(18)—both require validation by accepted standards. Thus, Rule 201 uses the term "known" to mean what is "not subject to reasonable dispute"; and Rule 803(18) requires that the treatise ("written primarily and impartially for professionals, subject to scrutiny and exposure for inaccuracy") be "established as a reliable authority." *See* Rule 803(18) & Adv. Comm. Note.

Finally, the logic of Rule 702's requirement that the expert be "qualified . . . by knowledge, skill, experience, training, or education" supports the view that the testimony itself must have a sound foundation of validity in accepted standards. As one scholar has aptly noted, "Rule 702's requirement that the expert who testifies be qualified to do so would be incongruous, to say the least, and ludicrous, to speak the worst, if the scientific underpinning for the expert's opinion were not also qualified." Starrs, *Frye v. United States Restructured and Revitalized: A Proposal to Amend Federal Evidence Rule 702*, Jurimetrics J. 249, 251 (Spring 1986). Hence, the requirement of expertise itself insists that the testimony be more than mere personal belief, even by an individual with impressive credentials: its validity must be well-grounded according to independent community standards.[9]

[9] Significantly, in the Ninth Circuit, petitioners themselves, far from contesting the reading of Rule 702 as embodying the notion of "acceptance" in the relevant field, treated Rule 702 as reflecting just such a notion. Appellants' C.A. Reply Br. 9, 10 ("Courts apply Rule 702 to determine whether the principle, procedure or technique is generally accepted in the scientific community."; referring to "[t]he 'general acceptance' standard of Rule 702"). Petitioners argued only that Rule 702 does not apply to "the substance of the opinions" but only to "the *techniques* that are being analyzed." *Id.* at 10. This distinction, however, concedes that accepted standards

b. *Will Assist the Trier of Fact.* The natural "accepted-standards-for-validation" meaning of "scientific . . . knowledge" is reinforced by Rule 702's requirement that expert testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue." As an initial matter, the Rule is properly construed to require that each particular expert's testimony must "assist the trier of fact." It is unreasonable to read Rule 702 as petitioners do—that is, as indicating that if knowledge on a scientific issue would help the jury, then any expert may offer any view that is on the same topic, even if that particular testimony will *not* assist the trier of fact. *See* Pet. Br. 31-34. Any such reading is undermined by the Rule's careful tying of the expert's testimony (through the term "thereto") to the "scientific, technical, or other specialized knowledge [that] will assist the trier of fact." It is also contrary to the Advisory Committee's statement that "[w]hen opinions are excluded, it is because they are unhelpful." More pointedly, it is just not plausible to attribute to Congress an intent to allow the introduction of unhelpful expert testimony—which, by definition, petitioners' parsing of Rule 702 allows—on some sort of "in for a penny, in for a pound" theory.

The "will assist" standard, as applied to scientific assertions, necessarily "assumes that the evidence is based upon scientifically recognized and defensible methods." Amer. Soc. Law, Medicine & Ethics *Amicus* Br. 3. Scientific evidence, like other evidence, will not assist the jury in its *proper* task—understanding the evidence, then reaching a judgment that is based on evidence that actually has a reliable foundation, not just on evidence that the jury might believe is true—unless it has "scientific merit." Law Professors' *Amicus* Br. 8; *see id.* at 13, 15. Thus, the validity of an expert's assertion must itself have a reliable foundation—in the accepted standards

determine what can be testified to under Rule 702. In any event, it is hard to see how to derive petitioners' distinction from Rule 702.

appropriate to the validation of that type of assertion—in order for the claim to assist the trier of fact."[10]

c. *Rule 703.* Rule 703 confirms the essential prerequisite for admission of expert testimony—a foundation, or good grounds for acceptance as valid, based on the standards followed in the relevant field of expertise. Rule 703 governs the "bases of opinion testimony by experts." It provides that an expert may base an "opinion or inference" on any "facts or data" that are "perceived by or made known to the expert at or before the hearing": the bases thus may be (1) perceived at the hearing (the expert looks at the gun in evidence while on the stand); (2) perceived before the hearing (the expert tested the gun before trial); (3) made known at the hearing (the hypothetical question); (4) made known before the hearing (hearsay). *See* Rule 703, Adv. Comm. Note. Expert opinions based on data in the last category were inadmissible at common law and would, of course, be inadmissible under Rule 602's requirement of "personal knowledge" as a foundation for testimony. *See* Rule 703, Adv. Comm. Note; *see also* Rule 802. But Rule 703

[10] The same conclusion can and should be reached under Rules 401 through 403 (some of whose language the Ninth Circuit used in its opinion, J.A. 238). Thus, Rule 401, defining "relevance," directs the court to inquire into the "principles evolved by experience or science" to determine relevance (Rule 401, Adv. Comm. Note). Rule 403 then allows exclusion of evidence whose probative value is substantially outweighed by "unfair prejudice," *i.e.*, any kind of "undue tendency to suggest decision on an improper basis" (Rule 403 & Adv. Comm. Note). A foundation in valid principles is necessary for evidence to have probative value in the broadest sense, and the absence of a reliable foundation renders evidence an improper basis for decision. What Rule 702 makes explicit for expert testimony, therefore, can also be derived from the more general provisions of Rules 401-403. *See* Br. *Amicus Curiae* of Chamber of Commerce. Of course, the close relationship of these requirements is hardly surprising given the integrated nature of the Rules as a Code (*see* Rule 102); and that relationship explains the reference to the relevance rules in some of the cases dealing with scientific evidence.

makes an express exception to Rule 602 (which states that "[t]his rule [602] is subject to the provisions of rule 703, relating to opinion testimony by expert witnesses"), so as "to bring the judicial practice into line with the practice of the experts themselves when not in court." Rule 703, Adv. Comm. Note (observing that, *e.g.*, physicians base diagnoses on what would be hearsay statements in court, including statements of patients, relatives, nurses, and other physicians).

In deciding to broaden the permissible bases for expert opinions, however, Congress explicitly revealed the basic foundational principle that, as reflected in Rule 702, governs *all* expert testimony. Opinions based on otherwise inadmissible hearsay are to be admitted only if the facts or data are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Rule 703. The rule itself, in short, requires that the foundation for the opinion's validity conform to the accepted standards in the field, a requirement that brings Rule 703 "into line" (Adv. Comm. Note) not only with accepted scientific practice but with the foundational requirement of Rule 702. Rule 703, therefore, even as it eliminates a pre-existing evidentiary impediment to the admission of properly validated expert opinions, makes clear that those opinions must be properly validated under community standards.

2. *The Rules of Evidence as a Whole Confirm this Interpretation of Rule 702.*

Petitioners' "expert-qualification only" view of Rule 702 also reflects a fundamental misunderstanding of the place of Rule 702 in the Rules of Evidence as a whole. Seen in that context, Rule 702 can only be reasonably construed to serve the essential function of ensuring a reliable foundation appropriate to expert testimony, one that substitutes for the usual (but inapplicable) requirement of personal knowledge. Indeed, a judicially applied

foundation requirement is particularly important for expert testimony. By contrast, petitioners' view leads to the highly anomalous result that, among all witnesses, experts alone need not have a reliable foundation for their testimony.

a. Whereas petitioners concentrate virtually all of their "statutory context" discussion on the "relevancy" standards of article IV of the Rules (*see* Pet. Br. 19-28), they all but ignore (*but see id.* at 32 n.61, 36) the second overarching requirement for admissibility of evidence: a proper "foundation," or basis for validity, without which even relevant evidence cannot be admitted. Rule 602, Adv. Comm. Note. This requirement is every bit as important as the requirement of relevancy, for it gives effect to "the common law insistence upon the most reliable sources of information." Rule 602, Adv. Comm. Note (internal quotation marks omitted). And it is every bit as pervasive: Rule 602 declares in sweeping terms that testimony must be based on "personal knowledge." Article VII's provisions regarding expert testimony, as well as Article VIII's provisions regarding hearsay testimony, are then extensively concerned with carefully crafting exceptions to that pervasive requirement. *See* Law Professors *Amicus* Br. 21 ("Articles VI, VII, and VIII designate whole areas in which otherwise relevant evidence is excluded.").[11]

It is within the setting of this fundamental and pervasive insistence on a reliable foundation that Rule 702 must be understood.[12] After all, article VII's rules on

[11] Likewise, articles IX and X impose certain restrictions on the admission of writings and similar evidence—again insisting on a foundation in reliability (through authentication and identification, Rules 901-903, and the general requirement of an "original," Rule 1002), over and above the mere requirement of relevancy.

[12] Rule 701 addresses lay opinion testimony. It insists that any lay opinion be "rationally based on the perception of the witness." It would seem that by a parity of reasoning an expert's opinion must also be "rationally based" on the material that is its foundation.

expert testimony are placed in the Rules after, and as an explicit exception to, Rule 602's (and 701's) broad restriction of testimony to what is based on personal knowledge—a standard that scientific generalizations of the sort at issue here can rarely if ever meet. *See* Rule 602 (referring to Rule 703). It makes little sense to attribute to Congress, in the context of this broad and traditional insistence on an adequate foundation to assure reliability of testimony, a decision to abandon any such requirement when it comes to expert testimony, demanding instead only that the expert be qualified. It is far more plausible to read article VII as requiring, for all expert assertions, a reliable foundation that substitutes for the usual guarantee of personal knowledge.[13]

b. The judge's function in applying this foundation requirement for the admission of expert testimony is an entirely familiar and expressly authorized one, thus refuting any suggestion that construing Rule 702 to embody a foundation requirement somehow interferes with the function of the trier of fact. The Rules explicitly assign to the judge the critical function of shaping, and limiting, the body of evidence that will ultimately be presented to the trier of fact for fact finding. Rule 104(a) instructs the judge to make all determinations not only of the qualifications of a witness but, in addition, of the "admissibility of evidence"—determinations that often include factual inquiries. *See* Rule 104(a), Adv. Comm. Note. And Rule 104(b)—recognizing that no evidence stands in isolation but becomes a proper basis for a

[13] Indeed, the hearsay exceptions in article VIII were explicitly crafted with an eye toward just such substitute guarantees. *See* Art. VIII, Adv. Comm. Note (following common-law approach to recognize exceptions only "under circumstances supposed to furnish guarantees of trustworthiness"); Rule 803(24) ("circumstantial guarantees of trustworthiness"); 804(b)(5) (same). Article VII is naturally construed likewise to require a reliable foundation.

rational decision only through connection to valid principles and the other evidence in the case—instructs the judge to keep track of, and insist upon, the need for each piece of evidence to be connected up to other evidence so as to ensure that "the foundation evidence is sufficient." Rule 104(b), Adv. Comm. Note.[14]

In short, the Rules explicitly impose on judges the duty to screen evidence based on its substance. It would be an extraordinary abdication of this judicial function to treat expert testimony as the one kind of testimony not screened for a reliable foundation by judges. It is hardly surprising, therefore, that every federal circuit agrees that the Rules contemplate precisely such a foundational inquiry for expert testimony.[15]

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[14] *Barefoot v. Estelle*, 463 U.S. 880 (1983), which is relied on by petitioners (Pet. Br. 39), hardly contradicts these clear provisions of the Rules. For one thing, it is a constitutional case, not decided under the Federal Rules of Evidence. Moreover, *Barefoot* involved a dispute, not over the admissibility of the substance of the testimony, but only over whether the testimony could be offered by an expert in his expert capacity. The Court emphasized that it had previously decided that the particular fact determination (a prediction of dangerousness) was one that lay jurors could make and so found no reason as a matter of due process to forbid expert testimony on that same issue. In any event, the Court in *Barefoot* did not undertake a full analysis of the Federal Rules or purport to hold, what Rule 104 makes impossible, that there is no ordinary screening function for federal judges, by which they ensure not only relevancy but a foundation as well. Later decisions, of course, have confirmed this function. *See Huddleston v. United States*, 485 U.S. 681 (1988); *Bourjaily v. United States*, 483 U.S. 171 (1987).

[15] The disagreement among the circuits concerns the nature of the testimony-specific foundation requirement, not the existence of such a requirement; and no circuit has treated the relevant standards in the expert's field as irrelevant to the foundational inquiry. Thus, for example, the Third Circuit in *DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d 941 (1990), and *United States v. Downing*, 753 F.2d 1224 (1985), though rejecting (on policy grounds) both the "general acceptance" standard and a rule excluding testimony based on unreviewed, unpublished materials, endorsed no rule even remotely resembling that advanced by petitioners here. Rather,

c. A reliable foundation for testimony is of greater, not lesser, importance when *expert* testimony is at issue. It has long been recognized, as Learned Hand observed in 1901, that expert testimony has a heightened potential to sway a jury "because of its aura of special reliability and trustworthiness." *United States v. Amarel*, 488 F.2d 1148, 1152 (9th Cir. 1973). *See* Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 50-52 (1901). At the same time, juries often have a diminished capacity to assess expert testimony on its merits. *See* Tribe, *Trial by Mathematics: Precision and Ritual in the Legal Process*, 71 Harv. L. Rev. 1329, 1331 (1971).

Lay factfinders' difficulty with assessing expert testimony on its merits has at least two aspects. First, the jury may simply not be able to understand the testimony —at least not well enough to resolve disputes between experts on complex matters of statistical and other scientific inference. Second, evaluating an expert claim on its merits is not just a matter of understanding it well enough to assess the "internal" soundness of the expert's reasoning. At least for scientific experts, there is an additional step. Because science is empirical, evaluation is a matter of testing the claim against reality—seeing how it fits with all of the available evidence and attempting to replicate the evidence underlying it. But the finder of fact in a judicial proceeding simply cannot do what scientists would often do to resolve disputes of the sort that a "battle of the experts" can produce: carefully review the available literature and, if that proved inconclusive, conduct new

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the factors enumerated in *Downing, including* general acceptance, demand that the trial judge screen expert testimony to determine "the soundness and reliability of the process or technique used in generating the evidence." 753 F.2d at 1237. And when the district court followed that approach on remand in *DeLuca*, a Bendectin case involving substantially the same oft-recycled packet of evidence as was proffered here, it held that the testimony lacked an adequate foundation. *See DeLuca*, 791 F. Supp. at 1057-59; Comment, *DeLuca v. Merrell Dow Pharmaceuticals, Inc.: Statistical Significance and the Novel Scientific Technique*, 58 Brooklyn L. Rev. 219 (1992).

experiments or studies. Indeed, if even the process of peer review for publication lacks the resources to undertake this complete process (Chubin *Amicus* Br. 11), it is fanciful to imagine that a jury, faced with two opposite presentations of evidence (each shaped by litigation strategy), could set about to survey the relevant literature, conduct new experiments or studies, and come to its own view of the validity of the asserted scientific generalization.[16] A foundation filter, therefore, is particularly important for expert testimony.[17]

3. *The Pre-1975 Background of the Rules Supports this Interpretation.*

The final reason for concluding that Rule 702 imposes a validation-based foundational requirement is that such a requirement has long and uniformly been recognized at common law. It would thus be surprising, to say the least, to think that Congress had intended to eliminate this requirement without ever saying so anywhere in the legislative proceedings leading to the enactment of the

[16] Of course, juries customarily rely on demeanor in judging a witness's veracity in reporting personal observations. But except for cases of falsification of data, veracity is rarely the issue when judging the validity of a scientific proposition. *See* P. Medawar, *Advice to a Young Scientist* 39 (1979) ("*[T]he intensity of a conviction that a hypothesis is true has no bearing on whether it is true or false.*") (emphasis in original).

[17] Petitioners acknowledge that "[o]n the issue of causation in a toxic tort case, common sense dictates that the jury is incapable of making a decision without the benefit of expert testimony." Pet. Br. 33. But if the jury cannot decide the causation issue without expert assistance, and it is incapable of independently resolving a technical battle of the experts, it cannot rationally decide the causation issue. Of course, as we have noted, neither the interpretation we offer here nor even more stringent ones can eliminate all "battles of the experts." *See* note 8, *supra*. But that recognition, based on the limitations of scientific knowledge, hardly supports the let-it-all-in approach urged by petitioners. It is far more sensible to suppose that Congress wanted to limit this sometimes-inevitable battle to disputes over well-founded contested theories or situations where the application of such theories reasonably can lead to different conclusions.

Federal Rules. On the contrary, the natural and well-accepted inference in these circumstances is that Congress intended to perpetuate the prior practice. *See United States v. Abel*, 469 U.S. 45, 51-52 (1984) (given "state of unanimity" regarding evidentiary practice before the Federal Rules, it is "unlikely that [Congress] intended to scuttle [it]" without providing a clear indication of such intent). *See also* Pet. Br. 23 n.49 ("the common-law background can be pertinent to interpreting *ambiguities* in the Rules").

There is no dispute in this case that, prior to 1975, the federal courts required that expert scientific testimony had to rest on a foundation that met the standard of "general acceptability" in the scientific community. While that principle is often referred to as the "*Frye* rule" (*Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923)), the policy underlying the approach had been recognized earlier. *See* Hand, *supra*. By 1975, the requirement was pervasive. *See United States v. Alexander*, 526 F.2d 161, 163 n.3 (8th Cir. 1975) (the "federal courts of appeals continue to subscribe to [the] 'general scientific acceptability' criterion") (citations omitted); *United States v. Skeens*, 494 F.2d 1050, 1053 (D.C. Cir. 1974); Giannelli, *The Admissibility of Novel Scientific Evidence:* Frye *v.* United States, *a Half-Century Later*, 80 Colum. L. Rev. 1197, 1228-29 (1980). Most state courts likewise followed such a standard. *Ibid.*; P. Giannelli & E. Imwinkelreid, *Scientific Evidence* § 1-5, at 10-11 (1986).

As petitioners implicitly concede, however, there is not a word in the Advisory Committee Notes or in any hearing, report, or floor debate in Congress that states an intent to abandon that approach. *See* Giannelli, *supra*, at 1229; P. Giannelli & E. Imwinkelreid, *supra*, at 29. In these circumstances, as the Court in *Abel* held specifically with respect to the Federal Rules, the customary inference is that Congress was working no radical unannounced change in the governing standard. *See* S.

Saltzburg & M. Martin, *Federal Rules of Evidence Manual* 15 (5th ed. 1990); Giannelli, *supra*, at 1228-29. *See generally Pennsylvania Dep't of Pub. Welfare v. Davenport*, 495 U.S. 552, 563 (1990); *United Sav. Ass'n v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 380 (1988); *Emil v. Hanley*, 318 U.S. 515, 521 (1943).

To be sure, this inference of presumed continuity may be defeated if the statutory text disproves it. *See Bourjaily v. United States*, 483 U.S. 171 (1987). In this case, however, there is no basis for rejecting the inference. Rather, the text of Rule 702, through its requirement that the expert testify to "scientific . . . knowledge [that] will assist the trier of fact," reinforced by Rule 703, with its "reasonably relied upon by experts" standard, affirmatively embodies a foundational requirement that carries forward the basic idea governing pre-1975 federal court practice: that a claim be tested for an adequate foundation under accepted standards for validation. *See* Law Professors' *Amicus* Br. 5 n.3 ("the generally prevailing view appears to situate [*Frye*] in Rule 702"); Imwinkelreid, *The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony*, 67 N.C. L. Rev. 1, 1-2 (1988); P. Giannelli & E. Imwinkelreid, *supra*, § 1-5, at 29-30.

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In summary, a straightforward application of traditional principles of statutory construction demonstrates that Rule 702 of the Federal Rules of Evidence requires a judicial determination not only (1) that resolution of a question warrants the use of expert testimony and (2) that a particular expert is qualified in his or her field, but also (3) that the testimony proffered by an expert rests on a foundation reflecting the generally accepted standards in that field for validating expert assertions. Petitioners have come forward with no basis for supposing that this

long-standing, common-sense requirement was omitted by Congress.[18]

B. For Some Scientific Claims, The Necessary Foundation Requires Out-Of-Court Passage Through The Process Of Scientific Community Scrutiny And Verification; For Other Claims, The Foundation Requires Conformity Of The Underlying Reasoning To Accepted Scientific Standards For Validation Of That Type Of Claim.

Application of the "accepted standards" foundational requirement of Rule 702 directly leads to two doctrinal rules for scientific testimony. In the scientific community, the accepted standards for validation of a claim depend largely on the nature of the claim. Some claims—typically those stating a general scientific proposition—simply cannot have a reliable foundation if they have never passed

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[18] Petitioners' challenge to the foundational rule as improperly judge-made (Pet. Br. 16-28) is beside the point because, as just shown, the requirement is squarely located in Rule 702. For that reason, this case presents no opportunity to consider the scope of interstitial lawmaking authority conferred on the federal courts under the Federal Rules of Evidence. *See* Rule 102 ("[t]hese rules shall be construed to secure . . . promotion of *growth and development of the law of evidence* to the end that the truth may be ascertained and proceedings justly determined") (emphasis added).

Similarly, petitioners' argument based on *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), also rests on the conclusion that the courts below applied a "judge-made rule." Pet. Br. 41. While their *Erie* analysis is probably flawed even on that assumption (*see Byrd v. Blue Ridge Rural Elec. Coop., Inc.*, 356 U.S. 525 (1958)), the argument is obviously frivolous in view of the fact that the evidentiary requirement we rely on is part of the Federal Rules, which were enacted by Congress. Even petitioners do not suggest that *Erie* bars Congress from enacting a statute governing the reliability of judgments in the federal courts. (We also note that, because many States adopt testimony-specific reliability screens at least as demanding as we suggest, petitioners' proposal itself would apparently cause outcome-determinative divergence from state evidentiary practice as much as, if not more than, our interpretation: evidence excluded in state court would, in petitioners' view, be admitted in federal courts in the same case.)

the test of out-of-court scientific community scrutiny. Other claims—typically those applying accepted scientific propositions to particular historical occurrences—must be assessed in court for conformity of their reasoning to accepted standards of validation.

1. *Some Scientific Claims Cannot Have an Adequate Foundation Without Community Scrutiny and Verification.*

It is an essential precondition to the validation of certain types of scientific claims that they be "accessible to the skepticism of the larger scientific community." Carnegie Comm'n *Amicus* Br. 27. It is "under the glare of pluralistic criticism" (*id.* at 5) that the necessary process of independently scrutinizing a scientist's reasoning process, attempting to replicate the results, and questioning for consistency with other relevant evidence goes forward.[19] Indeed, for that reason, scientific practices that inhibit independent scrutiny of results are recognized as even *ethically* questionable. *See Responsible Science* 5-6, 25, 28, 140; *see also* note 19, *supra*. Thus, it is central to the meaning of "scientific knowledge," as applied to certain types of scientific claims, that it "is the product of a *collective* human enterprise to which scientists make individual contributions which are purified and extended by mutual criticism and intellectual cooperation" and "has been through a thorough process of criticism by well-motivated and skillful experts who have not been able to detect any significant errors." J. Ziman, *Reliable Knowledge* 2-3, 108 (1978).

[19] *See* 1 Panel on Scientific Responsibility and the Conduct of Research, Committee on Science, Engineering, and Public Policy, National Academy of Sciences, *Responsible Science: Ensuring the Integrity of the Research Process* 20 (1992) ("scientific judgment, experimentation, and error-correction . . . are intrinsic to the development of new scientific knowledge"); *id.* at 25 ("Science is not only a body of information, composed of current knowledge, theories, and observations, but also the process by which this body of knowledge is developed. Furthermore, the scientific process is a social enterprise that involves individuals and institutions engaged in developing, certifying, and communicating research results."); Rothman *Amicus* Br. 8 (" 'replication' . . . is fundamental to science. . . . 'Replicating' is the process by which one scientist tries to verify the procedures and analyses undertaken by other scientists.").

This requirement—a requirement of the scientific community itself—normally applies to general propositions that, not being statements of historical fact, must be equally true in every scientist's laboratory and that can only be established by repeated testing against the evidence of observation and experiment. Of course, the most basic requirement of this understanding of "scientific knowledge" is that a scientific hypothesis be written up, with supporting reasons, and disseminated to the scientific community for the process of independent scrutiny and verification to get under way. And this requires that a proposition be found in the "literature" to which that community normally turns, which assuredly does not include courtroom transcripts.

Where scientific generalizations are asserted, an individual scientist cannot claim "scientific knowledge" based simply on that individual's unreviewed analysis—especially if the "analysis" is unwritten or fails explicitly and in detail to set out its data, premises, and methodology. There are too many opportunities for error, particularly on matters where no individual scientist may even know of all the research being done simultaneously elsewhere in the world and where reasoning, such as statistical inference, is difficult and fraught with potential for mistake. It is the writing up of a chain of reasoning and evidence, followed by independent scrutiny and acceptance, that normally defines a scientific generalization as "scientific knowledge."[20] An assertion that has not been sub-

[20] *See* Black, *A Unified Theory of Scientific Evidence*, 56 Ford. L. Rev. 595, 601 (1988) (science "relies on the give and take of criticism, testing, experimentation, and review to determine what is valid"); D. Hull, *Science as a Process* 361-62 (1988) ("Science

mitted to this community process cannot lay claim to that status. *Cf.* Rule 803(18), Adv. Comm. Note (learned treatises reliable because "written primarily and impartially for professionals [and] subject to scrutiny and exposure for inaccuracy").[21]

Several of petitioners' *amici* appear to dispute this contention, claiming that the decision below will unduly rigidify scientific thinking by insisting on universal (or near universal) agreement before a proposition can be testified to in court. These concerns are fanciful: our approach to testimony about generic scientific principles that can reasonably be subjected to general community scrutiny does not require "unanimity" or exclude testimony based on one side of a genuine debate in the scientific community. Instead, it requires (where appropriate) that a scientist write up his or her analysis and disseminate it through normal channels calculated to reach those independent scientists interested in the problem and capable of evaluating the hypothesis; it then allows the scientist

is a social process in which scientists evaluate and criticize each other's work, leading to successive improvement."); *id.* at 367 ("If science is to be cumulative and self-correcting, then it is inherently social."); *id.* at 377 ("If science is a selection process, transmission is necessary.").

[21] Contrary to petitioners' worry (Pet. Br. 47-49; *see also* Chubin *Amicus* Br.), this requirement does not insist rigidly on "peer reviewed publication," even for generalizations that require community scrutiny for acceptable validation. Notably, the Ninth Circuit did not hold otherwise: its legal requirement was submission of a written paper to the scientific community for "verification and scrutiny by others in the field." J.A. 240. In some circumstances, certainly, this process can appropriately take place through other means of dissemination, such as government reports or reports by expert bodies. What is essential—a *necessary*, not a *sufficient* condition—is dissemination of full written reasoning through normal channels of scientific communication. It is because peer reviewed publication is the usual means of communication in the fields relevant to this case, and indeed encompassed the heart of the material petitioners' witnesses either sought to contradict or "reanalyze," that the Ninth Circuit correctly referred to this process.

to establish a foundation for the claim that the hypothesis has passed the scientific process of community scrutiny, if there is in fact reasonable independent agreement that this hypothesis is valid under accepted scientific standards and a reasonable explanation of the basis for disagreeing with dissenting scientists.[22]

Contrary to the suggestion of one of petitioners' *amici*, moreover, the Ninth Circuit's insistence on this rational process of scientific inquiry does not promote a mistaken and destructive image of science, one that treats certain views as simply unworthy of consideration and that conjures up Seventeenth Century images of "establishment" condemnation of "heresy." *See Amicus* Br. of Physicians, Scientists, *et al.* at 7-16. Far from resting on a view of science as enforcing orthodoxy, Rule 702's and Rule 703's incorporation of scientific standards for validating claims necessarily assumes that the scientific process is precisely the opposite of "closed." These rules treat the scientific process as open to new ideas and ready and willing to entertain and, ultimately, to be convinced by them. This may not have been a fair assumption at the time of Galileo, but the very reason for allowing scientific testimony, and for referring to scientists' standards for validation, is that Congress has determined that it is a correct assumption today—even with the inevitable de-

[22] It is worth noting here that the legal system sensibly does not treat evidence in precisely the same way as does the scientific community. At least theoretically, the scientific community stands ready to consider all evidence. But the federal legal system, like every state system as far as we are aware, places limits on the types of evidence that are reliable enough to serve as a basis for a legal judgment: the pervasive requirement of personal knowledge is one such limit; the conceded requirement of witness "qualification" is another. Restricting the bases for a legal judgment—which may place a person in prison or drive a beneficial medicine off the market—in no way conflicts with the commitment of *science* to consider all evidence.

mand of the scientific community that revolutionary theories have a burden to meet in proving themselves.[23]

More important, perhaps, it is petitioners' view, rather than ours, that would have a stifling effect on the scientific process. Their view inevitably places a premium on experts' *withholding* their analyses from the ordinary channels of communication among scientists: under petitioners' approach, such analyses would be admissible for litigation purposes regardless of dissemination through normal scientific channels; and there are powerful incentives to refrain from formal written presentation or publication outside the legal arena, because such restraint reduces both the material available for cross-examination and the risk of professional refutation (as well as professional embarrassment). Petitioners' view thus would predictably foster a separate world of "litigation science."

2. In-Court Assessment of a Claim for Conformity to Accepted Standards Is Otherwise Necessary to Establish a Foundation.

The accepted scientific standards for testing *some* scientific propositions for validity do not require passage through the process of community dissemination, scrutiny,

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[23] *Amici* cite as an example the "resistance" to a theory of electrical communication by the nerve systems of plants. Br. 15. Even aside from the nature of the source relied on—a newspaper account, quoting the participants, with their natural inclination to portray the "human story" as one of a lonely fight for recognition against closed minds—there is nothing in this example to suggest that anything occurred other than the natural process of scientists insisting that "revolutionary" theories prove themselves by solid evidence. Not even *amici* suggest that the proponents of the new theory had such evidence before they announced what *amici* themselves call their "discovery" (*id.* at 15).

Indeed, one of petitioners' *amici* has aptly written elsewhere: "A man cannot wear the mantle of Galileo simply because he stands against the establishment that treats him badly: he must also be right, or at least brilliant." S.J. Gould, *Zealous Advocate*, 176 Science 623, 625 (1972) (book review).

and verification. Thus, a case-specific diagnosis of an individual patient; a generalization that is so narrow as to be of no interest to available publications, means of communication, or other scientists; or a newly discovered claim that there has been no time to submit for community scrutiny in any formal way—these would, by dint of necessity, not be disqualified from having an adequate foundation by failure to pass through the normal community processes. In these situations, the foundational validity required by Rule 702 can be judged only by an in-court assessment of the evidence and reasoning offered in support of the claim, measured against accepted standards for validating that kind of claim. Indeed, where the underlying data are themselves inadmissible, Rule 703 by its express terms independently requires just such a determination, insisting that the grounds for the claim be "of a type reasonably relied on by experts in the particular field in forming opinions or inferences upon the subject."

This in-court inquiry into the sufficiency of the foundation for expert opinion testimony necessarily has two components: (1) the proper materials must be used—where bricks are required, sawdust will not do; and (2) those materials must be used in a reasonable fashion—although bricks may be a proper component in constructing a house, bricks alone, without mortar, are insufficient to sustain the structure. The foundational requirement thus demands inquiry not only into the raw data relied on by an expert, but also into the processes used to develop and integrate those data before an opinion may properly be based on it. Indeed, the Advisory Committee Note to Rule 703 emphasizes this point by reference to "public opinion poll evidence," as to which courts are instructed, in determining admissibility, to direct their attention "to the *techniques employed*" (emphasis added) —that is, not just to the fact that the expert is relying on responses of people surveyed, but also to the sampling methodology, including the size of the sample, the ques-

tions asked, the responses counted or not counted, etc. It was just such an analysis that was undertaken by the case cited in the Advisory Committee Note as a model, *Zippo Mfg. Co. v. Rogers Imports, Inc.*, 216 F. Supp. 670 (S.D.N.Y. 1963). *See also United States v. Esle*, 743 F.2d 1465, 1474 (11th Cir. 1984) (rejecting expert opinion under Rule 703 based on untrustworthy market survey).[24]

Ignoring the inescapable relationship between Rules 702 and 703 (*see* pp. 18-19, *supra*), petitioners fasten only on the language in the latter rule providing that the "facts or data" used by an expert need not be admissible in evidence if they are "of a type reasonably relied upon by experts in the field." According to petitioners, this means that as long as an expert uses "data that scientists generally rely upon in formulating an opinion," the opinion must be admitted regardless of the expert's methods or reasoning process. Pet. Br. 37. This isolated parsing of the words of Rule 703 demonstrates how nonsensical petitioners' reading of the Rules is.[25] Thus, in

[24] This approach has repeatedly been followed by the lower federal courts in determining the admissibility of scientific testimony in numerous areas. *See, e.g., Head v. Lithonia Corp.*, 881 F.2d 941, 943 (10th Cir. 1989) (expert opinion that plaintiff suffered from head injury, which is based on topographical brain mapping, is inadmissible because this technique is not generally relied on by others in the field); *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 422-23 (5th Cir. 1987) (reliance on incomplete family history bars opinion on causation of injury); *Barrel of Fun, Inc. v. State Farm Fire & Casualty Co.*, 739 F.2d 1028, 1033 (5th Cir. 1984) (expert cannot base opinion on voice stress analysis); *United States v. Trunowski*, 659 F.2d 750, 755 (7th Cir. 1981) (even though sun charts generally relied on by experts in the field, use of chart for purpose of rendering opinion on date of photographs is prohibited because "chart had never been verified in usage for th[at] particular purpose").

[25] Petitioners go so far as to suggest that expert testimony would be admissible even if it were based on facts or data *not* reasonably relied on by experts in the field, as long as the expert personally observed the data. This conclusion follows directly from petitioners'

petitioners' view, if their experts took the numbers in an epidemiological study, put them into a computer, and repeatedly pushed "randomize," the experts could then base their opinion on the results of any one of those outcomes that they chose. Similarly, if they took a published study, relied on the helpful data and arbitrarily excluded the unhelpful data, they could then testify to an opinion based on their biased selection of the data. We doubt that Congress intended to countenance such results.[26]

C. Petitioners' Proffered Expert Testimony Doubly Fails To Meet The Necessary Foundation Requirement.

Petitioners must prove by a preponderance of the evidence that Bendectin caused their limb defects. To establish that case-specific claim, in the face of the uniformly negative epidemiological studies on Bendectin's properties in this regard, petitioners could not and do not rely on mere anecdotal, unsystematic medical opinion. Rather, they must and do offer expert scientific testimony to a general proposition about Bendectin's intrinsic properties —that the medication causes limb defects in babies who otherwise would not suffer them.[27]

reading of Rule 702 coupled with their principal reading of Rule 703, which they claim "provides no textual support for placing special limitations on expert testimony." Pet. Br. 35.

[26] The illogic of petitioners' "data-base" interpretation of Rule 703 is further demonstrated by a distinction that even petitioners feel constrained to draw. At one point in their argument, petitioners acknowledge that "it is plausible to argue" that an expert opinion in a Bendectin case based on "the alignment of the planets" would be inadmissible under Rule 703. Pet. Br. 37 n.66. But there is no substantive difference between an expert who looks to the planets when his or her gaze should be earthbound and one who is properly looking skyward in order to count the planets but concludes that the number is seven by inexplicably refusing to count Jupiter and Saturn. Opinions based on either ground are equally lacking in foundation under accepted scientific standards and are equally inadmissible.

[27] More particularly, as discussed below, petitioners must establish an increased rate of limb defects high enough to support the

Both courts below found, in accord with four other federal circuits, that accepted scientific standards do not allow an inference that Bendectin caused petitioners' limb reduction defects to be drawn based on the data and reasoning used by petitioners' experts. Thus, in addition to the inadmissibility of the general propositions about Benedectin's inherent properties in the absence of community scrutiny and verification, petitioners' crucial expert testimony was also inadmissible because of the aberrant and unreliable mode of reasoning by which they reached their necessary ultimate conclusion.

1. *Petitioners' Novel Claim about Bendectin's General Properties, Contradicting Uniform Published Analyses, Cannot Be Validated Without Passage Through the Normal Channels of Communication for Scientific Community Scrutiny and Verification.*

The generalization that Bendectin causes human limb defects is a classic empirical generalization, validated only through the process of community scrutiny. Any claim to this effect necessarily must include careful statistical analyses of large volumes of data, or at least arguments about the propriety of drawing inferences from animals to humans in the face of massive human data. Any such analyses and arguments must be carefully examined and criticized by others in the field. And a new conclusion like that offered by petitioners' experts, even if facially plausible, must be tested not only against a mountain of available evidence but against new studies designed to resolve any apparent conflict.

Yet none of petitioners' experts has ever set out in writing the data, premises, and methodology leading to the suggested conclusion: they have not submitted to community scrutiny through normal scientific channels,

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inference that, absent any other information, it is more likely than not that Bendectin, rather than another (unknown) agent, was the cause of the limb defects of any particular child whose mother took Bendectin.

much less gained independent acceptance for, an analysis purporting to explain the basis for concluding that Bendectin causes human limb reduction defects. The experts who rely on non-human evidence have never written and submitted for community scrutiny an argument that a legitimate inference of human causation can be drawn based on such evidence. And the experts who rely on human epidemiological evidence have never written up and disseminated their statistical analyses, along with an argument justifying the conclusions they base on the analyses and explaining why they think the published literature is wrong.

Nor can any of these experts claim a valid excuse: these are not brand new discoveries, too fresh to publish; these are not narrow claims of little interest to available publications or to other scientists. On the contrary, the topic is among the most thoroughly researched and publicized in the relevant scientific fields. In these circumstances, failure to submit formally reasoned papers making this claim to the normal channels of peer communication, aside from suggesting that the claims could not withstand community scrutiny, leaves the claim without an adequate foundation in the methods scientists themselves use to validate such claims. The expert testimony is therefore inadmissible.[28]

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[28] On this record, the only published work concerning Bendectin and birth defects by any of petitioners' experts is a one-paragraph "abstract" published by Dr. Swan. That is patently inadequate to establish a foundation, and the reason is worth stressing. Dr. Swan nowhere set out her assumptions or reasoning in the abstract; yet when one key assumption was later examined in *Lynch*, *supra*—using as the control group, not the entire universe of non-Bendectin users, as the Centers for Disease Control had done, but instead children affected with Down's syndrome and other genetic disorders—it was found unwarranted and misleading. 830 F.2d at 1195. An unelaborated report of a reanalysis is no basis for the scientific community even to begin the process of scrutiny and verification of how the reanalysis was done—what data were used, how they were classified, what statistical techniques were used, what inferences are

2. *The Claim of Petitioners' Experts Cannot Be Validated, Under Accepted Scientific Standards, by the Types of Data and Methodology They Use.*

The testimony of petitioners' experts is inadmissible for another reason as well. The experts rely on animal studies, chemical structure analyses, and unpublished "reanalyses" of other scientists' epidemiological studies to support their conclusion that "Bendectin is a human teratogen." Pet. Br. 4. Given the vast body of published epidemiological studies on the relationship between Bendectin and birth defects, however, these other materials are *not* "of a type reasonably relied upon" by experts in the field. As the Ninth Circuit correctly concluded, "the available animal and chemical studies, together with [petitioners'] expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused [petitioners'] injuries." J.A. 241; *cf. id.* at 234-35 (district court) ("expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks [a] sufficient foundation").

a. At the outset, it is important to stress the specific nature of petitioners' burden of proof here—causation of their own injuries by Bendectin under a preponderance standard. Petitioners ignore this point and rely instead

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asserted based on the analysis, how those inferences fit with other available evidence—and whether the conclusion drawn is warranted. *See* J. Casti, *Paradigms Lost* 61 (1989) ("Science is defined in terms of *how* and *why* we know something, not *what* we know. . . . What makes a theory a serious contender is not just the theory, but the theory plus the arguments that support it.").

We note that, after summary judgment was granted in this case, petitioners' expert, Dr. Newman, published a letter to the editor in the Journal of the American Medical Association. 264 J. Amer. Med. Ass'n 569 (Aug. 1, 1990). That letter, of course, is not part of the record on summary judgment. But even that letter purports to do no more than describe certain non-epidemiological studies; it does not make any argument for an inference based on such studies, much less an argument that explains away the massive epidemiological evidence.

on government and scientific publications stating that animal data are sufficient grounds for deciding *other* issues, such as whether to keep a product off the market, to engage in further research, or to recommend harmless and inexpensive protective measures. *See, e.g.*, Pet. Br. 5. But these uses of animal evidence are all quite different from the use needed to support the claim of causation at issue here.[29]

Thus, in deciding whether to keep a new product off the market, there is no suggestion that the government is making a "more-likely-than-not" retrospective determination. On the contrary, any non-frivolous cause for concern may be sufficient for this purpose: even a quite small likelihood of toxicity might readily justify delaying (for further research at least) the introduction of such a product.[30] Indeed, in making a prospective determina-

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[29] The affidavit of petitioners' expert Dr. Swan illustrates this point. Using the form of the double negative, she states that "one cannot draw a conclusion from [the epidemiological studies] that Bendectin does not cause limb reduction defects." She then states: "when there is data consistent with increased risks, as with Bendectin, [we should] conclude that it is more probable than not that Bendectin is associated with birth defects." J.A. 116. But "data consistent with increased risks" includes everything but conclusive demonstration of no increased risk. Her reasoning therefore transforms a mere possibility into a 50% probability.

More generally, petitioners are attempting to take the premise that epidemiology is not a powerful enough tool to disprove the mere *possibility* that Bendectin (or any other drug) is a teratogen at some very low level, and to leap from that basis to the conclusion that Bendectin is a teratogen at more than a doubling level (*see* p. 40, *infra*). This is but another form of unjustified reliance on animal and chemical studies to prove much more than they are capable of proving, not only using them to shift the epidemiological burden of proof, but also to magnify the significance of epidemiology's inability to disprove a negative conclusively.

[30] *See* Amer. Soc. Law, Medicine & Ethics *Amicus* Br. 2-3, 4 ("the purposes and processes of regulatory agency proceedings, aimed at prospective risk elimination, differ sufficiently from retrospective jury damages trials and . . . the same evidentiary standards would not apply"; "Where the question is whether . . . there is a

tion of risk, animal data and chemical analyses will often be the *only* information that experts can rely on: until a product is brought to market, extensive human data will almost never be available. Petitioners' approach, in short, ignores the obvious fact that a foundation admittedly strong enough to support a hundred-pound weight does not *ipso facto* support a thousand-pound weight.

Given the present state of scientific knowledge, moreover, when it comes to a "more-likely-than-not" causation requirement with respect to limb defects, the fact is that petitioners are seeking to shoulder a heavy burden indeed. As the Fifth Circuit has aptly observed, "[a]ssuredly, one day in the future, medical science may have a clearer understanding of the mechanics of tissue development in the fetus. However, that is not the case today." *Brock*, 874 F.2d at 315. It is undisputed that "[i]n ninety-five percent of the cases of limb reduction . . . the cause is unknown." *Lynch*, 830 F.2d at 1193 (citing testimony of petitioners' expert here, Dr. Alan Done, and of Dr. Murray Feingold, Physician-in-Chief at the National Birth Defects Center). On the other hand, it is likewise undisputed that the overwhelming majority of women that used Bendectin did *not* give birth to children with limb reduction.

These undisputed facts mean that direct proof of causation in a birth defect case is impossible: experts can rely only on circumstantial proof through statistical inference. And when that kind of evidence is advanced to satisfy a more-likely-than-not burden of proof requirement, a plaintiff can carry the burden only by showing that the odds are at least *twice as great* that a woman who takes Bendectin will have a child with a limb defect than a woman who does not take the drug. *See DeLuca*, 911 F.2d at 958 ("to avoid summary judgment, the rela-

risk of harm from a particular chemical exposure, the range of relevant, admissible scientific evidence might, under Rules 702 and 403, be broader than where the issue is one of actual causation related to a particular individual's injury.").

tive risk of limb reduction defects arising from the epidemiological data [an expert] relies upon will, at a minimum, have to exceed '2' "). *See* Comment, *Causal Inference in Epidemiology: Implications for Toxic Tort Litigation*, 71 N.C. L. Rev. 247, 280-85 (1992).

b. In finding petitioners' foundation wanting, both courts below rested essentially on two conclusions: (1) that *only* human data could provide a reasonable basis for an opinion that Bendectin caused petitioners' injuries; and (2) that the human data relied on by petitioners' experts were not of a "type reasonably relied upon" in answering that question. We address each point separately and show that both are correct.[31]

i. To begin with, the district court correctly ruled that "[a]bsent a scientific understanding of the cause of the birth defects at issue in Bendectin cases, causation may be shown only through reliance upon epidemiological [human] evidence." J.A. 230 (citing *Richardson; Lynch; In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987)); *see also* J.A. 239 (court of appeals). There is virtually universal consensus in the field of teratology that human data are needed to show causation—in contrast to mere risk (*see* pp. 38-40, *supra*). In fact, according to current authorities, more than 1200 substances are considered to be animal teratogens, while only 30 substances are known human teratogens. *See* Shepard, *Catalog of Teratogenic Agents*, p. xiii (7th ed. 1992). Consequently, it is well recognized that "[e]xperimental work with animals can be suggestive, but never conclusive, that a drug may be tera-

[31] The Ninth Circuit reviewed the district court's conclusion that petitioners' causation evidence was inadmissible under a *de novo* standard. J.A. 238-39. Since the district court had ruled for respondent, that review standard is more advantageous to petitioners than more deferential ones like abuse-of-discretion. If, as we argue, the Ninth Circuit's ruling was correct, there is no need here to decide whether a more deferential standard of appellate review is warranted.

togenic to humans. In human populations, we are limited to what can be learned by means of epidemiological methods." Heinonen, Slone, & Shapiro, *Birth Defects and Drugs in Pregnancy* 6 (Wright 1983).

Even many of petitioners' experts agree with this view. For example, in *Richardson*, Dr. Done, who has aptly been characterized as "the primary causation expert [for plaintiffs] in numerous [Bendectin] cases" (*DePyper v. Navarro*, No. 83-303-467, slip op. 25 (Mich. Cir. Ct. June 13, 1989); *see* J.A. 230-33), testified that " 'before you can make a conclusion that a substance is teratogenic in humans, you must look to the human data' " (857 F.2d at 830 (citing Tr. 1104)); more specifically, " 'you would not give an opinion as to causation without a statistically significant association in humans between the ingestion of a drug and a cause of birth defects' " (857 F.2d at 831).[32] Similarly, in *Brock*, Dr. Glasser, also one of petitioners' experts here, "admitted that the only way to tell whether a substance is teratogenic in humans is to look to the human experience." 874 F.2d at 314. And to the same effect, Dr. Palmer, another of petitioners' experts here, testified in his deposition in this case, "I don't make an extrapolation from nonhuman animals to humans . . . Those discussions are without value." Palmer Dep., Tr. 443. *See generally*, *Lynch*, 830 F.2d at 1194 ("*in vivo* animal studies, *in vitro* animal studies, and the study of 'analogous' chemicals . . ., singly or in combination, do not have the capability of proving causation in human beings") (citing district court decision at 646 F. Supp. at 865-66, detailing numerous examples of plaintiffs' expert testimony to this effect).[33]

It is hardly surprising, therefore, that all five circuits to have ruled on the issue have held that animal data and chemical analyses are not a proper foundation on which to rest a conclusion that Bendectin causes limb defects in humans. And in the sixth case, *DeLuca*, the plaintiffs themselves deemed the contention so insubstantial that they did not challenge the district court's ruling (following the magistrate) barring the admission of such evidence. 911 F.2d at 946 n.8. In short, as Judge Weinstein explained in a landmark decision in this area, "sound epidemiological studies . . . are the only useful studies having any bearing on causation" in a toxic tort case. *In re "Agent Orange" Product Liab. Litig.*, 611 F. Supp. at 1231.

Not surprisingly, given this formidable body of precedent, petitioners nowhere argue that the non-epidemiological evidence is a sufficient basis for their experts' testimony. Instead, they attempt to support their conclusions by aggregating these bases with the admittedly insufficient human data. Pet. Br. 6-12. But this attempt

[32] Petitioners stress the controversy some epidemiologists have raised about the standard use by epidemiologists of a 95% confidence level as a condition of statistical significance. Pet. Br. 8-10. *See also* Rothman *Amicus* Br. It is hard to see what point petitioners' discussion establishes that could help their case.

Petitioners' experts have never developed and defended a detailed analysis of the epidemiological data using some alternative well-articulated methodology. Nor, indeed, do they show (or could they) that with some other plausible measure of confidence (say, 90%) the many published studies would collectively support an inference that Bendectin caused petitioners' limb reduction defects. At the very most, all that petitioners' theoretical speculations do is question whether these studies—as the medical profession and regulatory authorities in many countries have concluded—affirmatively prove that Bendectin is *not* a teratogen. But that is hardly a help to petitioners, because it is they who have the burden of proof.

[33] Petitioners' reliance on so-called "chemical structure" analyses is likewise misguided. As the courts of appeals generally have found, this kind of analysis has no power in the face of strong epidemiological data demonstrating no human effect. *See, e.g.*, *Richardson*, 857 F.2d at 829-30. Even on their own terms, petitioners' chemical analyses are useless because they compare Bendectin not to a substance "known to cause limb reduction birth defects" (Pet. Br. 7), but to a substance (an antihistamine) about which, in the words of petitioners' expert Dr. Done, at most a " 'suspicion' " has been raised. *Richardson*, 857 F.2d at 830. This pyramiding of speculations does not add up to probative evidence.

to prove causation by cumulating two insufficient kinds of facts or data must fail: it cannot produce a foundation that is reasonably relied on to establish the requisite opinion testimony here.

The animal data, as we have said and as petitioners' own experts indicate, can point to areas of possible risk and thus directions for further reasearch. But when that further research is strongly negative, it is unreasonable to add the animal studies that provoked the research to the negative conclusions resulting from it and come out to a positive conclusion. In short, the only proper foundation for the causation finding at issue here is human data. That is precisely what petitioners' expert, Dr. Done, has testified to—"you could not give an opinion as to causation without a statistically significant relationship in *humans*" (*Richardson*, 857 F.2d at 831 (emphasis added))—and to the extent that petitioners' expert opinions do not rest on such a foundation, they cannot be adequately propped up by animal data and chemical analyses.

ii. Turning then to the human data relied on by petitioners' experts, we begin by noting that of the eight experts proffered by petitioners (*see* Pet. Br. 2-3 & n.5; J.A. 232), only *one*, Dr. Palmer, is prepared to offer the opinion that "Bendectin did cause the limb defects in each of the [petitioners]." J.A. 192. The others conclude (at most) only that "there is a statistical *association* between Bendectin and limb defects." J.A. 152 (Glasser) (emphasis added); *see, e.g.*, J.A. 117 (Swan: "Bendectin is associated with birth defects, including limb defects"). But this latter conclusion—even if repeated numerous times—cannot support a jury verdict for petitioners. *See* pp. 40-41, *supra*. As the Sixth Circuit recently pointed out, "plaintiffs' experts stop short of testifying that Bendectin more probably than not caused the birth defects in babies. They have no factual or theoretical basis for a stronger hypothesis." *Turpin*, 959 F.2d at 1359-60.

Consequently, in our view, petitioners' submission here ultimately stands or falls with Dr. Palmer's testimony. But the bases for his testimony are self-evidently insufficient to support its conclusion. He claims that, in forming his opinions, "I have reviewed various *pieces* of scientific data and literature pertaining to Bendectin. I have specifically reviewed what I believe to be *all of the animal studies pertaining to Bendectin*." J.A. 190 (emphasis added). But no expert, "when not in court" (Rule 703, Adv. Comm. Note), would rely on that admittedly incomplete set of facts and data to formulate the opinion that Dr. Palmer is prepared to offer. Beyond that, while Dr. Palmer does not even indicate what epidemiological data he looked at, he nevertheless opines that "epidemiological data is the *least* reliable [in determining whether Bendectin is a teratogen]." J.A. 191 (emphasis added). These statements indicate that the available epidemiological data, which Dr. Palmer acknowledges not having thoroughly researched, played little, if any, role in forming his opinion; and he plainly did not rely on any data showing a statistically significant relationship between Bendectin and limb defects in humans.

That foundation cannot reasonably support the opinion that Bendectin causes limb defects, much less the more demanding opinion that Dr. Palmer offers—that these two petitioners' defects were caused by Bendectin. As the Sixth Circuit recently ruled in a case where Dr. Palmer offered essentially the same testimony: "the evidence cited in support of [Dr. Palmer's] conclusion is insufficient to meet the plaintiffs' burden of proof. Dr. Palmer does not testify on the basis of the collective review of his scientific discipline, nor does he take issue with his peers and explain the grounds for his differences. *Indeed, no understandable scientific basis is stated.* Personal opinion, not science, is testifying here." *Turpin*, 959 F.2d at 1360 (emphasis added). *See also Cadarian v. Merrell Dow Pharmaceuticals, Inc.*, 745 F. Supp. 412 (E.D. Mich. 1989) ("Dr. Palmer has failed to cite facts or data of a type reasonably relied upon by experts in his

field in support of the opinion that Bendectin was a proximate cause of [plaintiffs'] birth defects").[34]

Moreover, even if petitioners' other expert testimony, claiming merely that Bendectin is "associated with limb defects," could suffice to raise a triable issue on causation (*but see* p. 44, *supra*), petitioners would still lack admissible evidence: those less ambitious opinions likewise do not rest on an adequate epidemiological foundation. Both in this Court and in the district court, petitioners focus in this regard solely on Dr. Glasser's opinion, presumably because, in their view, his opinion is most reliably based on the epidemiological data. Pet. Br. 7 & nn. 21-25; Plaintiffs' Opp. To Defendants' Motion for Sum. Judg. at 19. But his proposed testimony, much like that of his colleagues, simply does not rest on facts or data "reasonably relied upon by experts in the . . . field."[35]

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[34] Dr. Palmer claims that he examined the medical records of petitioners' mothers' in reaching his conclusions. J.A. 192. But all he concludes from this "examination" is the undisputed fact that these women took Bendectin during the early months of their pregnancy. That fact, of course, says nothing about whether Bendectin *caused* the defects.

[35] As the district court's opinion in this case indicates (J.A. 230-31), petitioners relied in part on Dr. Alan Done to provide a "reanalysis" of the epidemiological data. (Petitioners originally listed him as a witness; subsequently withdrew his name and substituted Dr. Palmer; but then attached some of Dr. Done's testimony in another case to their opposition to summary judgment.) Yet petitioners barely mention Dr. Done in this Court. *See* Pet. Br. 5 n.9.

The reason is evident: Dr. Done and the substance of his testimony have both been thoroughly discredited. As to Dr. Done, the trial court in *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 563 A.2d 330 (D.C. 1989), *cert. denied*, 493 U.S. 1074 (1990), found after an evidentiary hearing that Dr. Done "knowingly and intentionally gave false testimony at trial in six areas . . . related to his qualifications." *Id.* at 332. *But cf. id.* at 333-38 (ruling that any misrepresentations were insufficient to allow a new trial on a Rule 60(b)(6) motion). As to his testimony, the district court on remand in *DeLuca* found that Dr. Done's calculations were riddled

Thus, Dr. Glasser simply takes three of the numerous epidemiological studies that have been conducted and notes his disagreement with the researchers who found no statistically significant relationship between Bendectin and limb defects. He apparently bases this disagreement on the fact that these researchers used the customary 95% confidence level to determine statistical significance. But there are two problems that make this reliance unreasonable. First, Dr. Glasser accounts for only a tiny portion of the available epidemiological data, providing no reason as to why he rejects the numerous other studies. No responsible scientist relies on that kind of preselected data alone. *See, e.g.*, EPA, Proposed Guidelines For Assessing Male Reproductive Risk, 53 Fed. Reg. 24850, 24860 (June 30, 1988) ("[a]ll relevant data should be considered in risk assessments"). This is precisely the kind of "data dredging" that the Advisory Committee Note indicates violates the proscriptions of Rule 703. See pp. 33-34, *supra*. Second, although Dr. Glasser rejects the customary 95% confidence level generally relied on by scientists in this field (*see DeLuca*, 911 F.2d at 947-48,[36] he fails to provide, much less support the use of, some alternative standard. *See* note 32, *supra*. All that Dr. Glasser has done is to look for the highest Bendectin-correlation numbers in the array of epidemiological data and then conclude, *ipse dixit*, that "there is in fact a statistical association between Bendectin and birth defects including limb defects." J.A. 152. Teratologists, we submit, do not rely on that jury-rigged data base to reach

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with error, often incomprehensible, and downright misleading. *DeLuca*, 791 F. Supp. at 1047-54. *See also Lynch*, 830 F.2d at 1196 (rejecting Dr. Done's reanalysis); *Richardson*, 857 F.2d at 830-31 (same).

[36] Although the Third Circuit views the use of this level as "arbitrary," it nevertheless acknowledges that a 95% confidence level is a "common value on the tables scholars use to calculate significance" (911 F.2d at 947) and a "convention of [the epidemiology] discipline" (*id.* at 948).

the opinion put forth by Dr. Glasser. *See Brock*, 874 F.2d at 312 (similarly rejecting Dr. Glasser's epidemiological analysis).[27]

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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[27] Even if this Court adopts petitioners' view of the Rules and holds the evidence at issue admissible, the judgment below should still be affirmed. At a minimum, the foregoing analysis demonstrates that petitioners' evidence on the question of causation is simply insufficient, against the weight of respondent's scientifically validated and formally reviewed epidemiological evidence, to support a rational verdict finding causation. No materially different analysis being required, this is a proper alternative ground (argued below) in support of summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986).

APPENDIX

FEDERAL RULES OF EVIDENCE

Rule 102. Purpose and Construction

These rules shall be construed to secure fairness in administration, elimination of unjustifiable expense and delay, and promotion of growth and development of the law of evidence to the end that the truth may be ascertained and proceedings justly determined.

Rule 104. Preliminary Questions

(a) Questions of admissibility generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) Relevancy conditioned on fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

(c) Hearing of jury. Hearings on the admissibility of confessions shall in all cases be conducted out of the hearing of the jury. Hearings on other preliminary matters shall be so conducted when the interests of justice require, or when an accused is a witness and so requests.

(d) Testimony by accused. The accused does not, by testifying upon a preliminary matter, become subject to cross-examination as to other issues in the case.

(e) Weight and credibility. This rule does not limit the right of a party to introduce before the jury evidence relevant to weight or credibility.

Rule 401. Definition of "Relevant Evidence"

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 403. Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion, or Waste of Time

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Rule 602. Lack of Personal Knowledge

A witness may not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may, but need not, consist of the witness' own testimony. This rule is subject to the provisions of rule 703, relating to opinion testimony by expert witnesses.

Rule 701. Opinion Testimony by Lay Witnesses

If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b)

helpful to a clear understanding of the witness' testimony or the determination of a fact in issue.

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 703. Bases of Opinion Testimony by Experts

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Rule 803. Hearsay Exceptions; Availability of Declarant Immaterial

The following are not excluded by the hearsay rule, even though the declarant is available as a witness: . . .

(18) Learned treatises. To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.